REMARKS

In the Office Action of August 12, 2008, claims 1, 3-6, 10-12, 14, and 20-21 were rejected under Section 103(a) as being unpatentable over U.S. Patent No. 6,632,191 ("Headley") in view of U.S. Patent No. 4,985,153 ("Kuroda"). Claims 7 and 13 were rejected as unpatentable over Headley in view of Kuroda, and further in view of U.S. Patent No. 6,743,192 ("Sakota").

In response to the Office Action, new independent claim 28 has been added, while independent claims 1 and 20 have been amended to more particularly recite the claimed subject matter. For reasons that will be described in greater detail herein, it is submitted that these claims and the claims dependent therefrom are patentably distinct from the prior art of record, so it is respectively requested that these rejections be withdrawn and the presently pending claims be reconsidered and allowed.

Independent claim 1 has been amended to clarify that the fluid circuit in that claim includes at least two containers (referred to as "first" and "second" solely for the purpose of distinguishing them from each other, rather than implying any particular configuration or processing sequence) and quantities of whole blood are flowed thereinto. After the blood has been flowed into the containers, the blood source is disconnected from the fluid circuit. At least a portion of the quantity of whole blood in the first container is processed therein to separate it into the desired components for removal of at least a portion of one of the components from the first container. Processing of at least a portion of the other quantity of whole blood begins after the blood source is disconnected. This subject matter is disclosed in the application as filed (e.g., at paragraphs [00022]-[00026]), so it is respectfully submitted that it does not amount to the addition of new matter. New claims 22-26, which depend from claim 1, are similarly supported by the specification and/or figures as filed. As for dependent claims 3-7, they have been amended to correspond more closely to the terminology employed in claim 1 as amended.

Independent claim 20 has been amended to clarify that the fluid circuit includes a container, and whole blood from the source is flowed into the fluid circuit and the

container. After the blood has been flowed into the fluid circuit and container, the blood source is disconnected from the fluid circuit. At least a portion of the whole blood in the container is processed in the container to separate it into the desired components for removal of at least a portion of one of the components from the container. Processing of at least a portion of the quantity of whole blood in the fluid circuit begins after the blood source is disconnected. This subject matter is disclosed in the application as filed (e.g., at paragraphs [00022]-[00026]), so it is respectfully submitted that it does not amount to the addition of new matter. New claim 27, which depends from claim 1, is similarly supported by the specification and/or figures as filed. As for dependent claim 21, it has been amended to correspond more closely to the terminology employed in claim 20 as amended.

New independent claim 28 recites a method for collecting and separating whole blood into one or more components. A disposable blood separation fluid circuit is provided, the fluid circuit being adapted to cooperate with a reusable separation controller and including a fluid circuit. The fluid circuit includes a fluid flow path for communication with a blood source, a container in fluid communication with the fluid flow path, and a blood processing chamber in fluid communication with the container and the fluid flow path. The fluid flow path is connected to the blood source and quantities of whole blood are flowed into the blood processing chamber and the container. The blood source is disconnected from the fluid circuit after the blood has been flowed into the container. At least a portion of the whole blood in the processing chamber is processed to separate it into the desired components for removal of at least a portion of one of the components from the processing chamber. Processing of at least a portion of the quantity of whole blood in the container begins after the blood source is disconnected. This subject matter is disclosed in the application as filed (e.g., at paragraphs [00022]-[00026]), so it is respectfully submitted that it does not amount to the addition of new matter. New claims 29-31, which depend from claim 28, are similarly supported by the specification and/or figures as filed.

The methods of amended claims 1 and 20 and new independent claim 28 are clearly distinguishable from the prior art relied upon by the Examiner, either alone or when considered together. All of the independent claims recite methods wherein whole blood is flowed from a blood source to two locations. In claim 1, whole blood is flowed into two containers. In claim 20, whole blood is flowed into a container and a separate location within the fluid circuit. In claim 28, whole blood is flowed into a blood processing chamber and a container. At least a portion of the whole blood in one of these locations (one of the containers of claim 1, the container of claim 20, and the processing chamber of claim 28) is processed in that location, while processing of at least a portion of the quantity of whole blood in the other location does not begin before the source is disconnected.

Considering first Headley, it fails to teach or otherwise suggest a method of flowing whole blood into two locations. Instead, Headley provides only one location (rotor 21) into which whole blood is flowed prior to component separation and subsequent removal of a blood component from the location. While Headley does provide for multiple processing stages, all of the whole blood processed in each iteration is flowed into the same single location (rotor 21). There is no disclosure of a separate location into which whole blood is flowed, the processing of at least a portion of the whole blood in such location not beginning until after the blood source is disconnected from the system. Indeed, Headley fails to teach the claimed subject matter and provides no logical basis for modifying its methods to arrive at the claimed methods.

As for Kuroda, it similarly fails to provide two locations into which whole blood is flowed. Kuroda describes two embodiments, one with and the other without a blood collection bag 17. In the embodiment employing the blood collection bag 17, blood is flowed from a source into the bag 17 (column 4, lines 46-59; column 5, lines 15-19). When a sufficient amount of whole blood has been flowed into the bag 17, the whole blood is flowed through a filter means 2 into a primary bag 3 (column 5, lines 55-56; column 8, lines 62-64). Subsequently, the primary bag 3 is centrifuged to separate the filtered blood into its components (column 9, lines 13-22), which are later removed from

the primary bag 3 (column 9, lines 36-56). It will be seen that this embodiment of Kuroda fails to provide: (1) two locations into which whole blood is flowed and (2) a location into which whole blood is flowed and then processed therein. Whole blood is flowed into only one location (the blood collection bag 17) and the blood is not processed in that location. The fluid flowing into the primary bag 3 is processed therein, but constitutes filtered blood, rather than whole blood. Accordingly, the first embodiment of Kuroda fails to teach these two features of the claimed subject matter.

With regard to the second embodiment of Kuroda (i.e., the embodiment which omits a blood collection bag 17), it is substantially identical to the first embodiment, except whole blood is flowed directly from a source, through the filter 2, and into the primary bag 3 (column 5, lines 46-54). As in the first embodiment of Kuroda, there is no provision for: (1) two locations into which whole blood is flowed or (2) a location into which whole blood is flowed and then processed therein. In this embodiment, blood is only flowed into one location (the primary bag 3) and that blood has already been passed through a filter 2, such that the fluid entering and processed in the primary bag 3 is filtered blood, rather than whole blood. Hence, both embodiments of Kuroda fail to teach the claimed subject matter and provide no logical basis for modifying the associated method to arrive at the claimed subject matter.

Turning now to Sakota, it is similar to the second embodiment of Kuroda, in that whole blood is flowed from a source, through a filter F1, and into a processing bowl 12 (column 6, lines 53-58; column 7, lines 26-39). The filtered blood is separated into its components, which are subsequently expressed from the bowl 12 (column 7, line 54 – column 8, line 4). As described above with regard to the second embodiment of Kuroda, there is no provision for: (1) two locations into which whole blood is flowed or (2) a location into which whole blood is flowed and then processed therein. Blood is only flowed into one location (the processing bowl 12) and that blood has already been passed through a filter F1, such that the fluid entering and processed in the processing bowl 12 is filtered blood, rather than whole blood. Hence, Sakota fails to teach the claimed subject matter and provides no logical basis for modifying the described

method to arrive at the claimed subject matter. Further, the blood source is not disconnected from the system until the end of the procedure (column 10, lines 13-27), in contrast to the claimed methods, which provide for processing after the source is disconnected from the system.

As the prior art identified in the Office Action fails to teach or suggest the claimed subject matter or otherwise render it apparent, it is respectfully requested that the rejections of the pending claims be withdrawn.

CONCLUSION

For the above reasons, it is respectfully submitted that all of the claims are in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested.

Respectfully submitted,

COOK, ALEX, McFARRON, MANZO
CUMMINGS & MEHLER, LTD.

Date: December 12, 2008

By: /Joseph R. Freund/
Gary W. McFarron
Reg. No. 27,357
Joseph R. Freund
Reg. No. 55,191

200 W. Adams Street, Ste. 2850
Chicago, IL 60606
Phone: (312)236-8500
Fax: (312) 236-8176

Customer No. 69275